

Remarks

The Examiner has rejected the Claims 17-21 under 35 U.S.C. 103(a) as being unpatentable over Holtzman et al. (US 7,195,761) in view of Seiffert et al. (US 6,518,011). Applicants submit that this rejection is improper for the reasons stated below and respectfully assert that the Examiner has failed to set forth a *prima facie* case of obviousness. As such, Applicants request withdrawal of the rejection.

Applicants surprisingly discovered during the preparation of anti-A β antibodies that A β peptide (endogenously produced in most mammalian cell lines commonly used to express antibodies) binds to the expressed anti-A β antibody at low levels and is carried through the cell culture and purification process. This peptide contamination of recombinantly-produced anti-A β antibody material increases the potential for an increased immunogenic response in a patient. Furthermore, when the endogenously produced A β peptide is non-human (as with a CHO cell line) the immunogenicity implications for non-human A β peptide bound to the expressed anti-A β antibody may cause even greater concern for patient safety and, thus, make prevention, removal, or reduction of the A β peptide vitally important.

This discovery of endogenously produced A β in the preparation as a result of the peptide binding to the expressed anti-A β antibody has led to the development of processing conditions of the claimed invention. Considering that the A β peptide contamination of recombinantly-produced anti-A β antibody material was previously unknown, the solution to solving this problem cannot be obvious. "The Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor, would select the elements from the cited prior art references for combinations in the manner claimed." *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). Holtzman et al. in view of Seiffert et al. does not disclose or-even suggest that the problem of the present invention exists. It therefore follows that the skilled artisan would not be motivated by the cited prior art to identify the solution provided in the present invention.

Furthermore, none of Holtzman et al. or Seiffert et al. teach or suggest **the step of adding secretase inhibitors to media used to grow cells endogenously producing A β peptide and expressing the anti-A β antibody**. The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103.

Section 2143.03 of the MPEP requires the “consideration” of every claim feature in an obviousness determination. To render claims 17-21 unpatentable, however, the Office must do more than merely “consider” each and every feature for this claim. Instead, the asserted combination of the patents to Holtzman et al. and Seiffert et al. must also teach or suggest *each and every claim feature*. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” See *In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, Applicant submits that this is why Section 904 of the MPEP instructs Examiners to conduct an art search that covers “the invention *as described and claimed*.” (emphasis added). Lastly, Applicant respectfully directs attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int’l v. Teleflex Inc.* stated that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. See *In re Wada and Murphy*, *citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

Conclusion

Applicants assert that the Examiner has failed to meet the necessary burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a) and that Holtzman et al. in view of and Seiffert et al. do not suggest or teach the claim limitations of the present invention of adding secretase inhibitors to media used to grow cells that express the anti-Aβ

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antibody. In view of the above arguments and remarks, Applicants courteously solicit reconsideration of these rejections and passage of this case to issuance.

Respectfully submitted,

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